



#1 ————— May, 2004

Bulletin & Update

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

*The Committee for the Protection of Human Subjects (CPHS) will periodically release issues of the **Bulletin & Update** to inform researchers and others regarding important changes in CPHS procedures as well as State and National issues of importance for human subject protection in research. Copies of the **Bulletin & Update** will be distributed via e-mail to researchers as well as posted on the CPHS web site (www.oshpd.ca.gov/cphs).*

Important Changes in Project Protocol

For the first time in many years, the CPHS has instituted changes in the project protocol that researchers must use in submitting applications. The principal change is the inclusion of an item on conflict of interest.

New Projects: Principal investigators submitting new projects to the CPHS after May 7, 2004, must use the new protocol format. New project applications submitted after May 7, 2004 in the old format will not be reviewed and will be returned to the principal investigator for revision. A copy of the new protocol format has been included as an attachment to the e-mail transmitting this bulletin. Please consult the CPHS web site (www.oshpd.ca.gov/cphs), Instructions for Researchers, for full instructions on using the new protocol format.

Continuing Projects: Principal investigators may continue to submit periodic review and revision applications for previously approved projects using the old protocol format. **However, if the principal investigator for the project changes a conflict of interest statement equivalent to section #12 of the new protocol must be included in the cover letter for the next continuing project application.**

HIPAA

The CPHS, as a federally approved institutional review board, is empowered to grant waivers or alterations of patient authorization for the release of protected health information under the Health Insurance Portability and Accountability Act (HIPAA). For this purpose, a new section (#8) has now been included in the project protocol. Continuing projects requesting a HIPAA waiver or alteration should send a letter to the CPHS Administrator addressing all of the issues in section #8 of the new project protocol. If you will be using a database held by a California Health and Human Services Agency department, please confirm with the department whether you will need a HIPAA waiver for using the database. The Office of Statewide Health Planning and Development and the Office of Health Information and Research, Vital Statistics Section databases are not covered under HIPAA and do not require a HIPAA waiver for use.

Forms Changes

We have recently made two changes in the forms that CPHS uses for review and reporting:

1. The New Project Application and Review Checklist has replaced the three forms that were previously required for the **new** projects. Hopefully this one form will be easier for researchers to use than the previous three forms.

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2. There is a new Adverse Event Report Form to report the occurrence of an adverse event to the CPHS within 48 hours.

Since CPHS's use of forms is evolving, please consult the CPHS web (www.oshpd.ca.gov/cphs) site, Forms, for the most current forms before submitting an application.

Expedited Review

As many researchers are aware, the CPHS now conducts most of its business using an expedited review process. Most projects using pre-collected data and without direct human subject contact can qualify for expedited review. Some advantages of expedited review include:

- Only one original and three copies are required to be submitted
- Only one or two members of the CPHS review the project instead of requiring full committee approval
- Only four weeks are required to process an expedited review, unless there are revisions required by the CPHS members

Please consult the CPHS web site for further information about expedited review.

New CPHS Administrator and Members

Within the last several months CPHS has welcomed a new administrator and five new members. The new administrator is: **Roxana Killian, LCSW**, formerly with the California Department of Aging.

The new members are:

Patricia Kirkish, Ph.D., Consulting Psychologist, Department of Mental Health.

Richard Ko, Pharm.D., Research Scientist IV, Food and Drug Branch, Department of Health Services.

Steven Lubeck, Ph.D., Research Scientist Supervisor, Office of Statewide Health Planning and Development.

Juan Ruiz, M.D., Chief, Epidemiology Branch of Office on AIDS, Department of Health Services

Kurt Snipes, Ph.D., Acting Chief, Cancer Planning, Research and Disparities Section of Cancer Control Branch, Department of Health Services.

CPHS Web site

All of the issues addressed in this Bulletin & Update are addressed in greater detail on the CPHS web site @ www.oshpd.ca.gov/cphs. If you have not visited the site, please do so. You will discover our guiding principles from the Belmont Report in the **Welcome** section. **About Us** delineates the scope of authority of the CPHS. You will discover the CPHS's responsibilities in relation to HIPAA in **What's New**. The CPHS meeting location and dates are listed in the **Meetings** section while directions to the meeting site are given in the **Site Map**. The **Policies and Procedures** detail the structure and the operating procedures of the CPHS. A convenient compilation of federal and State statutes and regulations that concern the functioning and responsibilities of the CPHS may be found when you click the **Laws & Regulations** button. The most important sections for researchers are "**Instructions For Researchers**" and **Forms** as these sections contain directions for submitting applications and the forms that the applications must include.